UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,601	12/12/2003	Jonathan F. Smith	95-02	2496

23713 7590 10/04/2007

GREENLEE WINNER AND SULLIVAN P C
4875 PEARL EAST CIRCLE
SUITE 200
BOULDER, CO 80301

EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
10/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,601	SMITH ET AL.	
	Examiner	Art Unit	
	Robert M. Kelly	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-15 and 20-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/7/07; 8/8/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response to restriction requirement of 9/8/06 are entered.

Claim 16-20 are amended.

Claims 1-31 are pending.

Election/Restrictions

Claims 1-15 and 20-31 remain withdrawn as drawn to non-elected inventions.

Claims 16-19 are presently considered.

Response to Request – Rejoinder

Applicant requests rejoinder of the other inventions (p. 8 of the response of 8/8/07).

It is noted, as stated in the restriction requirement of 10/31/06, that the process claims of the same scope as that of a finding of otherwise-allowable product claims, may be rejoined at the time of so-finding otherwise allowable product claims. Applicant is forewarned, however, that rejoinder after final rejection is foreclosed, as such would necessarily amount to further consideration.

Information Disclosure Statement

Applicant's IDSs of 8/8/07 and 5/7/07 have been considered, signed, initialed and dated.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

In light of the amendments, the rejections of Claims 17-19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, are withdrawn.

To wit, the claims no longer recite the term "derived from".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 7,078,218, and, for Claim 17, also Slovin, et al. (1999) Proc Natl Acad Sci, USA, 96(10): 5710-15. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to methods of making alpha-viral particles of the same scope as the presently

claimed invention. Moreover, the specification teaches similar tumor antigens and viral antigens (e.g., detailed description and examples).

Hence, at the time of invention, the compositions would be obvious as the purpose of the methods is to produce such compositions and the patent teaches it can be done, hence, there is a reasonable expectation of success.

Still further although only a single tumor antigen is taught, Slovin teaches that multiple antigens for the tumor may be used to develop multivalent vaccines (e.g., ABSTRACT). Hence, at the time of invention, it would have been obvious to modify the methods in developing a vaccine to prostate cancer. The Artisan would have expected success as the patent teaches the vaccines work, and Slovin teaches the use of doing so to develop a multivalent vaccine to prostate cancer.

Claims 16 and 18-19 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 7,090,852, for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant specification covers similar VEE replicons for inducing immunity to viruses, and Claim 6 of the patent claims a composition of such replicons encoding up to several specific MBGV proteins, which is useful for inducing immune responses to the Marburg virus. Further, the instant specification teaches that the replicons may be used to induce immunity to any virus. Hence, the compositions claims are obvious over the patent, the Artisan would have been motivated to make them in order to produce immunity to the Marburg virus.

Moreover, the Artisan would have had a reasonable expectation of success, as the claim teaches that the compositions may be used as a vaccine.

Response to Argument – ODP against 7,090,852

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the patent is drawn to a composition of the same viral particles, and not a plurality of particles with distinct antigens (p. 9, last paragraph).

Such is not persuasive. Applicant's claims read on a plurality of the same particle, which each encode multiple antigens, as well as the composition Applicant is arguing is present. Further, the specification teaches the combination of distinct viral particles which are argued is claimed (summary of the invention).

Applicant argues that the compositions as claimed are made by a distinct process, stressing that the salt wash step is the important component of the process (p. 10, paragraph 1).

Such is not persuasive. Applicant is claiming the product via a product-by-process claim and compositions obtained do not differ. Hence, the product is the same, and therefore is an obvious member of the genera currently claimed, and is obviousness-type double patenting. Another method of making the same composition does not make the composition patentable again.

Claims 16 and 18-19 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-3 and 8-9 of U.S. Patent No. 6,783,939, for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences between the claims are that the patent claims are

drawn to specific viral proteins as antigens of HIV. However, the instant specification teaches any particular combination of such antigens (e.g., pp. 4-5, paragraph bridging). Hence, in view of the patent, it would have been obvious to make the instantly claimed invention. The Artisan would have been motivated to do so in order to produce the proteins in immune responses. Moreover, the artisan would have had a reasonable expectation of success, as the patent taught that such particle compositions could be so-used.

Response to Argument – ODP against 6,783,939

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the patent is drawn to a composition of the same viral particles, and not a plurality of particles with distinct antigens (p. 10, paragraph 4).

Such is not persuasive. Applicant's claims read on a plurality of the same particle, which each encode multiple antigens, as well as the composition Applicant is arguing is present. Moreover, the patent teaches that these compositions may comprise multiple particles with distinct antigens (summary of the invention).

Applicant argues that the compositions as claimed are made by a distinct process, stressing that the salt wash step is the important component of the process (pp. 10-11, paragraph bridging).

Such is not persuasive. Applicant is claiming the product via a product-by-process claim and compositions obtained do not differ. Hence, the product is the same, and therefore is an obvious member of the genera currently claimed, and is obviousness-type double patenting. Another method of making the same composition does not make the composition patentable again.

Claims 16 and 18-19 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-8, 10-15, 33-40, 44-49 and 51-77 of U.S. Patent No. 6,521,235, for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences between the inventions are the patent claiming specific viral replicons, claiming specific attenuating mutations, and specific viral antigens. Moreover, the claims of the patent, except claims 3-4, do not claim specific antigens to protozoa or bacteria or the genera of any viral antigens. However, the instant specification teaches attenuating mutations to the E1-E3 (e.g., p.6), and the specific attenuating mutations (the references cited in e.g., p. 6). Further, the patent teaches protozoa, bacterial, and viral antigens in general (e.g., cols. 5-6). Still further, the instant specification teaches the specifically claimed viruses for their antigens (e.g., p. 12). Hence, in light of US Patent No 6,521,235, it would have been obvious to make the instant invention. The Artisan would have been motivated to do so in order elicit immune responses, as taught in the patent. Moreover, the Artisan would have expected success, as the patent teaches such.

Response to Argument – ODP against 6,521,235

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the patent is drawn to a composition of the same viral particles, and not a plurality of particles with distinct antigens (p. 11, paragraph 4).

Such is not persuasive. Applicant's claims read on a plurality of the same particle, which each encode multiple antigens, as well as the composition Applicant is arguing is present.

Moreover, Applicant is forewarned that amendment will only force an ODP to be made with another piece of art, for example, Applicant's other patents, to make the composition as Applicant argues is claimed. Hence, if Applicant wishes to avoid unnecessary delay in issuance of a patent, Applicant is recommended to find another manner to distinguish the patent.

Applicant argues that the compositions as claimed are made by a distinct process, stressing that the salt wash step is the important component of the process (pp. 12-13, paragraph bridging).

Such is not persuasive. Applicant is claiming the product via a product-by-process claim and compositions obtained do not differ. Hence, the product is the same, and therefore is an obvious member of the genera currently claimed, and is obviousness-type double patenting. Another method of making the same composition does not make the composition patentable again.

Claims 16, 18-19 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32, 34-35, 37, 40, 42, 44-45, 47, 50-52, 54-55, 57, 60, 62, 64-65, 67, 70, 72, 74-75, 77, 80, 82, 84-90 of U.S. Patent No. 6,531,135, for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences between the claims are the patent claiming specific alphavirus replicons. Further, the specifications each direct the artisan to use encoding sequences from similar viruses (e.g., PATENT, col. 5). Hence, from the disclosure of the patent, it would have been obvious to make the instantly claimed invention. The Artisan would have been motivated

to do so in order to provide immune responses, as taught in the patent. Moreover, the Artisan would have had a reasonable expectation of success, as the patent teaches it can be done.

Response to Argument – ODP against 6,531,135

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the patent is drawn to a composition of the same viral particles, and not a plurality of particles with distinct antigens (p. 12, paragraph 4).

Such is not persuasive. Applicant's claims read on a plurality of the same particle, which each encode multiple antigens, as well as the composition Applicant is arguing is present. Moreover, Applicant is forewarned that amendment will only force an ODP to be made with another piece of art, for example, Applicant's other patents, to make the composition as Applicant argues is claimed. Hence, if Applicant wishes to avoid unnecessary delay in issuance of a patent, Applicant is recommended to find another manner to distinguish the patent.

Applicant argues that the compositions as claimed are made by a distinct process, stressing that the salt wash step is the important component of the process (pp. 12-13, paragraph bridging).

Such is not persuasive. Applicant is claiming the product via a product-by-process claim and compositions obtained do not differ. Hence, the product is the same, and therefore is an obvious member of the genera currently claimed, and is obviousness-type double patenting. Another method of making the same composition does not make the composition patentable again.

Applicant argues that the claims of the patent do not teach a group of proteins corresponding to an expression library, and hence, are distinct (pp. 12-13, paragraph bridging).

Such is not persuasive. More than one protein antigen from the same source is included. How does this differ from a library? Simple use of the word library does not make something distinct, it is the structure of the composition itself that makes it distinct.

Claims 16 and 18-19 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13, 16-17, 19, 23-35, 37-55, 57, and 61 of U.S. Patent No. 6,156,558, for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences between the instant claims and the patent claims are that the patent encompasses not only claims the generic alphavirus, but also claims specific viruses encompassed, and further comprises specific attenuating mutations. However the instant specification teaches attenuating mutations in general, and teaches the various specific viruses claimed. Moreover, the patent, while not specifically claiming antigens, does teach the use of viral antigens (e.g., col. 5). Hence, in light of the disclosure of the patent, the instantly rejected claims are obvious. The Artisan would have been motivated to make the compositions, as the patent teaches that such may induce immune responses. Moreover, the Artisan would have expected success, as the patent teaches such.

Response to Argument – ODP against 6,156,558

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the patent is drawn to a composition of the same viral particles, and not a plurality of particles with distinct antigens (p. 13, paragraph 4).

Such is not persuasive. Applicant's claims read on a plurality of the same particle, which each encode multiple antigens, as well as the composition Applicant is arguing is present.

Moreover, Applicant is forewarned that amendment will only force an ODP to be made with another piece of art, for example, Applicant's other patents, to make the composition as Applicant argues is claimed. Hence, if Applicant wishes to avoid unnecessary delay in issuance of a patent, Applicant is recommended to find another manner to distinguish the patent.

Applicant argues that the compositions as claimed are made by a distinct process, stressing that the salt wash step is the important component of the process (pp. 13-14, paragraph bridging).

Such is not persuasive. Applicant is claiming the product via a product-by-process claim and compositions obtained do not differ. Hence, the product is the same, and therefore is an obvious member of the genera currently claimed, and is obviousness-type double patenting. Another method of making the same composition does not make the composition patentable again.

Applicant argues that the claims of the patent do not teach a group of proteins corresponding to an expression library, and hence, are distinct (pp. 13-14, paragraph bridging).

Such is not persuasive. More than one protein antigen from the same source is included. How does this differ from a library? Simple use of the word library does not make something distinct, it is the structure of the composition itself that makes it distinct.

Claims 16 and 18-19 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-26, 28-29, 31-34, and 36-37 of U.S. Patent No. 6,541,010, for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences between the instant

claims and the patent's claims are that the patent has attenuating mutations encompassed, specific viruses encompassed, and no specific heterologous sequence claimed. However, the patent's specification teaches prokaryotic, eukaryotic, protozoa, and viral antigens (e.g., cols. 11-12, paragraph bridging). Moreover, the instant specification teaches to attenuate the same genes, and use of similar viral replicons. Hence, in view of U.S. Patent No. 6,541,010, the artisan would have been motivated to make the claimed invention. The Artisan would have also expected success, as the patent teaches that such can be done.

Response to Argument – ODP against 6,541,010

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the patent is drawn to a composition of the same viral particles, and not a plurality of particles with distinct antigens (p. 14, paragraph 4).

Such is not persuasive. Applicant's claims read on a plurality of the same particle, which each encode multiple antigens, as well as the composition Applicant is arguing is present. Moreover, Applicant is forewarned that amendment will only force an ODP to be made with another piece of art, for example, Applicant's other patents, to make the composition as Applicant argues is claimed. Hence, if Applicant wishes to avoid unnecessary delay in issuance of a patent, Applicant is recommended to find another manner to distinguish the patent.

Applicant argues that the compositions as claimed are made by a distinct process, stressing that the salt wash step is the important component of the process (p. 14, last paragraph).

Such is not persuasive. Applicant is claiming the product via a product-by-process claim and compositions obtained do not differ. Hence, the product is the same, and therefore is an obvious member of the genera currently claimed, and is obviousness-type double patenting.

Another method of making the same composition does not make the composition patentable again.

Applicant argues that the claims of the patent do not teach a group of proteins corresponding to an expression library, and hence, are distinct (p. 14, last paragraph).

Such is not persuasive. More than one protein antigen from the same source is included. How does this differ from a library? Simple use of the word library does not make something distinct, it is the structure of the composition itself that makes it distinct.

Claims 16-19 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/517,083, for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are that the patent's claims are drawn to VEE alphaviral replicons, and specific mutations to attenuate such particles. However, the instant specification teaches VEE replicons (e.g. , p. 12) and further teaches attenuating mutations in VEE are desirable (e.g., p. 20). Lastly, it should be noted that in 10/517,083, Applicant has specifically defined the article "a" or "an" to encompass multiples, and hence, all these claims are drawn to multiple antigens. Lastly, the 10/517,083 Application teaches all the same species from which the antigens are derived (e.g., pp. 27-29). Hence, the instantly rejected claims are obvious over that of the claims and specification of the other Application. The Artisan would have been motivated to make them, in order to produce immune responses. Moreover, the Artisan would have had a reasonable expectation of success, as the other Application teaches such use.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Argument – ODP against 10/517,083

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the rejection be withdrawn and reinstituted at the time the other Application is patented (p. 15, paragraph 3).

Such is persuasive, under modified basis. The rejection may be held in abeyance, to be addressed until the present claims, or the other Application is allowed, to be readdressed then. However, simply withdrawing the provisional rejection is not allowed under current prosecution practice.

Applicant argues that the other Application is drawn to a composition of the same viral particles, and not a plurality of particles with distinct antigens (p. 15, paragraph 4).

Such is not persuasive. Applicant's claims read on a plurality of the same particle, which each encode multiple antigens, as well as the composition Applicant is arguing is present. Moreover, Applicant is forewarned that amendment will only force an ODP to be made with another piece of art, for example, Applicant's other patents, to make the composition as Applicant argues is claimed. Hence, if Applicant wishes to avoid unnecessary delay in issuance of a patent, Applicant is recommended to find another manner to distinguish the patent.

Applicant argues that the compositions as claimed are made by a distinct process, stressing that the salt wash step is the important component of the process (p. 15, last paragraph).

Such is not persuasive. Applicant is claiming the product via a product-by-process claim and compositions obtained do not differ. Hence, the product is the same, and therefore is an

obvious member of the genera currently claimed, and is obviousness-type double patenting. Another method of making the same composition does not make the composition patentable again.

Applicant argues that the claims of the patent do not teach a group of proteins corresponding to an expression library, and hence, are distinct (pp. 15-16, paragraph bridging).

Such is not persuasive. More than one protein antigen from the same source is included. How does this differ from a library? Simple use of the word library does not make something distinct, it is the structure of the composition itself that makes it distinct.

Claims 16 and 18-19 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-9, 17-18, and 23-26 of copending Application No. 10/929,234, for reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the instant claims are drawn to a minimum of a generic pair of antigens from a virus, both specifications teach HIV, and the same antigens, and HIV-1, as well as the instant specification teaching each specific type of alphaviral replicon particle claimed, and teaching attenuating mutations to the same genes. Hence, in light of the teachings and claims of 10/929,234, the Artisan would have been motivated to make the presently claimed invention, as it is taught for inducing immune responses. Further the Artisan would have expected success, as the 10/929,234 Application teaches that it would work.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Argument – ODP against 10/929,234

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the other Application is drawn to a composition of the same viral particles, and not a plurality of particles with distinct antigens (p. 16, last paragraph).

Such is not persuasive. Applicant's claims read on a plurality of the same particle, which each encode multiple antigens, as well as the composition Applicant is arguing is present. Moreover, Applicant is forewarned that amendment will only force an ODP to be made with another piece of art, for example, Applicant's other patents, to make the composition as Applicant argues is claimed. Hence, if Applicant wishes to avoid unnecessary delay in issuance of a patent, Applicant is recommended to find another manner to distinguish the patent.

Applicant argues that the compositions as claimed are made by a distinct process, stressing that the salt wash step is the important component of the process (p. 17, paragraph 1).

Such is not persuasive. Applicant is claiming the product via a product-by-process claim and compositions obtained do not differ. Hence, the product is the same, and therefore is an obvious member of the genera currently claimed, and is obviousness-type double patenting. Another method of making the same composition does not make the composition patentable again.

Applicant argues that the claims of the patent do not teach a group of proteins corresponding to an expression library, and hence, are distinct (pp. 17, paragraph 1).

Such is not persuasive. More than one protein antigen from the same source is included. How does this differ from a library? Simple use of the word library does not make something distinct, it is the structure of the composition itself that makes it distinct.

Claims 16-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 24, and 25 of copending Application No. 11/132,711. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the other Application's claims are drawn to TC-83 viral replicons, and do not teach claim any particular heterologous sequences, the present specification teaches the use of TC-83 strain, because of its naturally attenuated phenotype (e.g., p. 17), and the other Application teaches all the same specifically claimed species of antigen (e.g., p. 25). Hence, in light of the teachings and claims of the 11/132,711 Application, it would have been obvious to make the present invention. The Artisan would have been motivated to do so in order to treat various disorders. Moreover, the Artisan would have expected success, as the other Application teaches it will work.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Argument – ODP against 11/132,711

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the other Application is drawn to a composition of the same viral particles, and not a plurality of particles with distinct antigens (p. 17, last paragraph).

Such is not persuasive. Applicant's claims read on a plurality of the same particle, which each encode multiple antigens, as well as the composition Applicant is arguing is present. Moreover, Applicant is forewarned that amendment will only force an ODP to be made with another piece of art, for example, Applicant's other patents, to make the composition as Applicant argues is claimed. Hence, if Applicant wishes to avoid unnecessary delay in issuance of a patent, Applicant is recommended to find another manner to distinguish the patent.

Note: Deferal of Provisional Rejections

In keeping with Applicant's request, the provisional rejections, although maintained, are now deferred until such time as this Application or a cited Application is allowed.

It is noted that the instant Application and the various other patents and Applications with at least one common inventor are subject to restriction requirements between the compositions, methods of making, and methods of using, precluding certain rejections under double patenting. However, future changes in such restriction requirements (i.e., rejoinder in the instant Application, or in another Application) may subject these claims to rejections not held above.

It is further noted that the various inventors have been quite prolific in the field of alphaviral replicons, attaining approximately 24 patents to date, and having another 13 Applications in various stages of prosecution. Applicant should beware that, depending on how these Applications, as well as the present Application is amended, new rejections may be imposed under double-patenting.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claim Rejections - 35 USC § 102

Claims 16 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by 7,078,218 to Johnston, et al.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Johnston teaches methods of making alphaviral particles (e.g., Claims) which can contain multiple antigens (e.g., col. 8, paragraph 2), and can be to viral sources (e.g., cols. 1-2, paragraph bridging).

Hence, the composition is anticipated.

Claims 16 and 18-19 remain rejected under 35 U.S.C. 102(e) as being anticipated by US PAT NO 6,521,235 to Johnston, et al., patented February 18, 2003; and

Claims 16 and 18-19 remain rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter, for reasons of record.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

With regard to the claims rejected in this section, Johnston teaches the alphaviral particle replicon compositions, as claimed, wherein the alphaviral replicons comprise coding regions for more than one antigen (e.g., Claims 16 and 18-19), and further, Johnston teaches that the antigens can come from various viruses, protozoa, and bacteria (e.g., col. 6; claims).

Response to Argument – 102, Johnston

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Johnston does not anticipate the claims (pp. 18-19, paragraph bridging).

Such is not persuasive. Applicant is claiming a product by process, and not a method itself. There is nothing in the claims to distinguish the obtained composition from that of Johnston.

Claims 16 and 18-19 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 7,090,852 to Hevey, et al., for reasons of record.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Hevey teaches alphaviral amplicon particle compositions, comprising multiple antigens of Marburg virus (e.g., ABSTRACT; cols. 4-6, col. 7, paragraph 5; and Claim 6).

Hence, Hevey anticipates the claims.

Response to Argument – 102, Hevey

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Hevey does not anticipate the claims (pp. 19-20, paragraph bridging).

Such is not persuasive. Applicant is claiming a product by process, and not a method itself. There is nothing in the claims to distinguish the obtained composition from that of Hevey.

Applicant argues that Hevey does not teach a population of viral particles each with distinct antigens (p. 20, paragraph 2).

Such is not persuasive. Applicant's claims read on the population of a single type replicon with multiple antigens encoded.

Claims 16 and 18-19 remain rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,783,939 to Olmstead, Patented 8/31/04, for reasons of record.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

As shown by claims 2-3 and 8-9, the Olmstead teaches compositions of alphaviral replicon particles, comprising one or more encoded antigens from gag, env, and pol. Hence, Olmstead anticipates the instant claims.

Response to Argument – 102, Olmstead

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Olmstead does not anticipate the claims (p. 21, paragraph 1).

Such is not persuasive. Applicant is claiming a product by process, and not a method itself. There is nothing in the claims to distinguish the obtained composition from that of Olmstead.

Applicant argues that Olmstead does not teach a population of viral particles each with distinct antigens (p. 21, paragraph 1).

Such is not persuasive. Applicant's claims read on the population of a single type replicon with multiple antigens encoded.

Claims 16 and 18-19 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,521,235 to Johnston, et al., Patented 2/18/03, for reasons of record.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Johnston teaches alphaviral replicon vectors (ABSTRACT), encoding more than one antigen (e.g., Claims 3-4), which may be of viral, protozoan, or bacterial origin (e.g., cols. 5-6).

Hence, Johnston anticipates the claims.

Response to Argument – 102, Johnston

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Olmstead does not anticipate the claims (p. 22, paragraph 1).

Such is not persuasive. Applicant is claiming a product by process, and not a method itself. There is nothing in the claims to distinguish the obtained composition from that of Olmstead.

Applicant argues that Olmstead does not teach a population of viral particles each with distinct antigens and that it is limited to 2 antigens, and therefore is not a library (p. 22, paragraph 1).

Such is not persuasive. Applicant's claims read on the population of a single type replicon with multiple antigens encoded. If such is not a library, when does more than one antigen become a library? Still further, there is no term "representative library in the claims" but only "corresponding to a nucleic acid expression library". Such necessarily embraces more than one protein from any library.

Claims 16 and 18-19 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,531,135 to Johnston, et al., Patented 3/11/03, for reasons of record.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Johnston teaches alphaviral replicon particles (e.g., ABSTRACT), encoding more than one antigen (e.g., Claims 34-35), which may be from several viral sources (e.g., col. 5).

Hence, Johnston anticipates the claims.

Response to Argument – 102, Johnston

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the argument to the '235 patent is also applied here (p. 23, paragraph 1).

The Examiner argues the same answer as given to the '235 patent.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Johnston does not anticipate the claims (p. 23, paragraph 2).

Such is not persuasive. Applicant is claiming a product by process, and not a method itself. There is nothing in the claims to distinguish the obtained composition from that of Olmstead.

The following pair of rejections is made with, alternatively, the PGPub and patent, of the same application, however for sake of compactness, the analysis is only directed to the patent, as the Application has the same disclosure.

Claims 16 and 18-19 remain rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent Publication No. 20020034521 to Lee, et al., Published 3/21/02 and

Claims 16 and 18-19 also remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,495,143, to Lee, et al., Patented 12/17/02, for reasons of record.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Lee teaches VEE replicon particles (e.g., col. 4), and compositions of such wherein the replicon particles encode a plurality of botulinum bacteria antigens (e.g., Claim 28).

Hence, Lee anticipates the claims.

Response to Argument – 102, Lee Patent and Publication

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Lee does not anticipate the claims (p. 24, paragraph 3).

Such is not persuasive. Applicant is claiming a product by process, and not a method itself. There is nothing in the claims to distinguish the obtained composition from that of Olmstead.

Applicant argues that with a maximum of 6 antigens, the composition is not a library (p. 24, paragraph 3).

Such is not persuasive. When does it become a library? At 7? More than one antigen is considered a library. Still further, there is no term "representative library in the claims" but only "corresponding to a nucleic acid expression library". Such necessarily embraces more than one protein from any library.

Claims 16 and 18-19 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,632,640 to Lee, et al., Patented 10/14/03, for reasons of record.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Lee teaches VEE replicon particle compositions encoding 2 distinct antigens of Staphylococcus aureus endotoxins (e.g., col. 3, paragraphs 2-3).

Hence, Lee anticipates the cited claims.

Response to Argument – 102, Lee

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Lee does not anticipate the claims (p. 25, paragraph 3).

Applicant argues that Lee does not teach a representative library of antigens (p. 25, paragraph 3).

Such is not persuasive. What is the definitive number for a library? More than whatever the patent used to reject teaches? A library is considered to be any more than one. Still further, there is no term "representative library in the claims" but only "corresponding to a nucleic acid expression library". Such necessarily embraces more than one protein from any library.

Claims 16 and 18-19 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,770,479 to Lee, et al., patented August 3, 2004, for reasons of record.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Lee teaches a composition of VEE replicons (e.g., EXAMPLE 2), encoding more than one antigen of anthrax (e.g., Claim 15).

Hence, Lee anticipates the cited claims.

Response to Argument – 102, Lee

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Lee does not anticipate the claims (p. 26, paragraph 3).

Such is not persuasive. Applicant is claiming a product by process, and not a method itself. There is nothing in the claims to distinguish the obtained composition from that of Lee.

Applicant argues that Lee does not teach a representative library of antigens (p. 25, paragraph 3).

Such is not persuasive. What is the definitive number for a library? More than whatever the patent used to reject teaches? A library is considered to be any more than one. Still further, there is no term "representative library in the claims" but only "corresponding to a nucleic acid expression library". Such necessarily embraces more than one protein from any library.

Claims 16 and 18-19 remain rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent Publication No: 2002/0164582 to Hart, et al., Published 11/7/02, for reasons of record.

Hart teaches VEE replicon particles (e.g., paragraph 0025), encoding several Ebola virus antigens (e.g., paragraphs 0025 and Claim 59). (It is noted that the composition claim states that the DNA encodes these proteins, but the specification teaches that the DNA may be used to make the replicon particles, and hence, this evidences that the particles would contain the same sequences.)

Response to Argument – 102, Hart

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Hart does not anticipate the claims (p. 27, paragraph 3).

Such is not persuasive. Applicant is claiming a product by process, and not a method itself. There is nothing in the claims to distinguish the obtained composition from that of Hart.

Applicant argues that Lee does not teach a representative library of antigens (p. 27, paragraph 3).

Such is not persuasive. What is the definitive number for a library? More than whatever the patent used to reject teaches? A library is considered to be any more than one. Still further, there is no term "representative library in the claims" but only "corresponding to a nucleic acid expression library". Such necessarily embraces more than one protein from any library.

Claims 16 and 18-19 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,517,842 to Hevey, et al., Patented 2/11/03, for reasons of record.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Hevey teaches VEE replicon particles (e.g., col. 2, paragraph 6), encoding one or more Marburg virus antigens (e.g., col. 3, paragraph 4).

Hence, Hevey anticipates the cited claims.

Response to Argument – 102, Hevey

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Hevey does not anticipate the claims (p. 27, paragraph 3).

Such is not persuasive. Applicant is claiming a product by process, and not a method itself. There is nothing in the claims to distinguish the obtained composition from that of Hevey.

Applicant argues that Hevey does not teach a representative library of antigens (p. 27, paragraph 3).

Such is not persuasive. What is the definitive number for a library? More than whatever the patent used to reject teaches? A library is considered to be any more than one. Still further, there is no term "representative library in the claims" but only "corresponding to a nucleic acid expression library". Such necessarily embraces more than one protein from any library.

Claims 16 and 18-19 remain rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,156,558 to Johnston, et al., Patented 12/5/00, for reasons of record.

Johnston teaches a plurality of alphaviral particles encoding a plurality of antigens (e.g., Claim 37). Moreover, Johnston teaches such antigens being from viral sources (e.g., col. 5).

Response to Argument – 102, Johnston

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Johnston does not anticipate the claims (p. 29, paragraph 3).

Such is not persuasive. Applicant is claiming a product by process, and not a method itself. There is nothing in the claims to distinguish the obtained composition from that of Johnston.

Applicant argues that Hevey does not teach a representative library of antigens (p. 27, paragraph 3).

Such is not persuasive. What is the definitive number for a library? More than whatever the patent used to reject teaches? A library is considered to be any more than one. Still further, there is no term "representative library in the claims" but only "corresponding to a nucleic acid expression library". Such necessarily embraces more than one protein from any library.

Claims 16 and 18-19 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 6,451,592 to Dubensky, et al., Patented 9/17/02; and

Claims 16 and 18-19 are also rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,451,592 to Dubensky, et al., Patented 9/17/02.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37

CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Dubensky teaches a composition of alphaviral replicons comprising multiple heterologous sequences (e.g., col. 3, paragraph 4). Moreover, such encoding heterologous sequences can be antigens to viruses (e.g., cols. 33-34, paragraph bridging).

Hence, Dubensky anticipates the claims.

Response to Argument – 102, Dubensky

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Johnston does not anticipate the claims (p. 30, paragraph 3).

Such is not persuasive. Applicant is claiming a product by process, and not a method itself. There is nothing in the claims to distinguish the obtained composition from that of Johnston.

Applicant argues that multiple sequences are taught by Dubensky, in a single particle, and that further this does not correspond to a library (p. 30, paragraph 3).

Such is not persuasive. The claims read on such compositions, and the library is considered to be more than antigenic entity.

Claims 16 and 18-19 remain rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,792,462 to Johnston, et al., Patented 8/11/98, for reasons of record.

Johnston teaches a composition of VEE replicons encoding more than one Lassa fever virus protein, which are in a composition, administered to BHK cells (e.g., EXAMPLE 4).

Hence, Johnston anticipates the claims.

Response to Argument – 102, Johnston

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Johnston does not anticipate the claims (p. 31, paragraph 3).

Such is not persuasive. Applicant is claiming a product by process, and not a method itself. There is nothing in the claims to distinguish the obtained composition from that of Johnston.

Applicant argues that multiple sequences are taught by Johnston, but only single sequences, according to the passages cited (p. 31, paragraph 3).

Such is not persuasive. The single sequence could be a single protein, and the antigens could be as small as 5 amino acids for recognition. Hence, the single protein contains multiple antigens on it, and corresponds to the library by being a protein from the library.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being obvious over 7,078,218 to Johnston, et al., and Slovin, et al. (1999) Proc Natl Acad Sci, USA, 96(10): 5710-15.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Johnston teaches methods of making alphaviral particles (e.g., Claims) which can contain multiple antigens (e.g., col. 8, paragraph 2), and can be to viral sources (e.g., cols. 1-2, paragraph bridging).

However, Johnston does not teach the use of a tumor antigens.

On the other hand, Slovin teaches that multiple antigens for the tumor may be used to develop multivalent vaccines (e.g., ABSTRACT). Hence, at the time of invention, it would have been obvious to modify the methods in developing a vaccine to prostate cancer. The Artisan

would have expected success as the patent teaches the vaccines work, and Slovin teaches the use of doing so to develop a multivalent vaccine to prostate cancer.

Claims 16-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,156,558 to Johnston, et al., Patented 12/5/00, Nestle, et al. (1998) Nature Medicine, 4(3): 328-32, and Smooker, et al. (2000) Vaccine, 18: 2533-40, for reasons of record.

It is noted that the Nestle reference is only supplied as the abstract, as the Examiner was unable to obtain the full reference prior to the date that this Action is submitted. However, such abstract is sufficient to describe the aspects required of the reference.

Johnston teaches the use of similar alpha-viral replicon particles, in vaccines. (E.g., ABSTRACT; col. 3, paragraph 4; col. 4, paragraph 2; cols. 7-8, paragraph bridging.) Moreover, Johnston demonstrates that the particles are sufficient to produce immune responses against foreign gene encoded proteins (e.g., FIGURE 3). However, Johnston does not teach a plurality of replicons encoding a plurality of antigens, or the use of antigens to cancer.

On the other hand, Nestle teaches a cocktail of peptides used to produce cancer immunity (e.g., ABSTRACT), and Smooker demonstrates that a library of genes may be administered to develop an immune response.

Hence, at the time of invention, it would have been obvious to make a plurality of alphaviral replicons encoding the different peptides of Nestle. The Artisan would have been motivated to do so to produce an immune response to cancer, using the method of Smooker instead of actual delivery of the polypeptides. Moreover, the Artisan would have had a reasonable expectation of success, as Smooker had demonstrated that a plurality of antigens

could have been so-delivered and Nestle teaches that the plurality of peptides produced immune response to cancer.

Response to Argument – 103, Smooker/Nestle

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Smooker/Nestle does not Obviate the claims (pp. 32-33, paragraph bridging).

Such is not persuasive. Applicant is claiming a product by process, and not a method itself. There is nothing in the claims to distinguish the obtained composition from that of Smooker/Nestle.

Applicant argues that the combination of Smooker/Nestle is a distinct approach for the library than presently taken (p. 33, paragraph 2).

Such is not persuasive. The composition still reads on the claims and corresponds to a library.

Applicant argues that the combination of references is impermissible hindsight, because there is no specific motivation (p. 33, last paragraph).

Such is not persuasive. KSR v. Teleflex precludes the argument of specific motivation.

Claim 16 and 18-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,156,558 to Johnston, et al., Patented 12/5/00, and Smooker, et al. (2000) Vaccine, 18: 2533-40, for reasons of record.

Johnston teaches the use of similar alpha-viral replicon particles, in vaccines. (E.g., ABSTRACT; col. 3, paragraph 4; col. 4, paragraph 2; cols. 7-8, paragraph bridging.) Moreover, Johnston demonstrates that the particles are sufficient to produce immune responses against foreign gene encoded proteins (e.g., FIGURE 3). However, Johnston does not teach a plurality of replicons encoding a plurality of antigens, or the use of antigens to protozoans.

On the other hand, Smooker teaches a library of epitopes, expressed on separate plasmids (a library), for immunizing mice against Plasmodium chabaudi, a protozoan (ABSTRACT).

Hence, at the time of invention, it would have been obvious to make a library of alphaviral replicon particles encoding different foreign antigens of the protozoan. The Artisan would have been motivated to do so to immunize mice, thereby providing increased protection from Plasmodium chabaudi. The Artisan would have also have a reasonable expectation of success, as not only had Johnston demonstrated that immune responses could also be elicited, but Smooker had demonstrated the library of encoded proteins could induce immune protection from such protozoan.

Response to Argument – 103, Smooker/Johnston

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Smooker/Johnston does not Obviate the claims (pp. 34, last paragraph).

Such is not persuasive. Applicant is claiming a product by process, and not a method itself. There is nothing in the claims to distinguish the obtained composition from that of Johnston/Smooker.

Applicant argues that the combination of Smooker/Nestle is a distinct approach for the library than presently taken (p. 33, paragraph 2).

Such is not persuasive. The composition still reads on the claims and corresponds to a library.

Applicant argues that the combination of references is impermissible hindsight, because there is no specific motivation (p. 33, last paragraph).

Such is not persuasive. KSR v. Teleflex precludes the argument of specific motivation.

Claims 16 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,235,290 to Brunham, Patented 5/22/01 and U.S. Patent No. 6,156,558 to Johnston, et al., Patented 12/5/00 and Smooker, et al. (2000) Vaccine, 18: 2533-40.

Brunham teaches a DNA vaccine against Chlaymidia (e.g., ABSTRACT) and further teaches to design a multivalent vaccine using various forms of the MOMP gene, in order to provide increased immunity to more strains of Chlaymidia (e.g., col. 5, paragraph 5).

Johnston teaches the use of similar alpha-viral replicon particles, in vaccines. (E.g., ABSTRACT; col. 3, paragraph 4; col. 4, paragraph 2; cols. 7-8, paragraph bridging.) Moreover, Johnston demonstrates that the particles are sufficient to produce immune responses against foreign gene encoded proteins (e.g., FIGURE 3).

Smooker teaches a library of epitopes, expressed on separate plasmids (a library), for immunizing mice against Plasmodium chabaudi, a protozoan (ABSTRACT).

Hence, at the time of invention, it would have been obvious to modify the composition of Brunham to contain different antigens of MOMP from different strains of chlaymidia in the

vectors of Johnston. The Artisan would have been motivated to do so to increase the number of chlaymidia strains to which an immune response is elicited. Moreover, the Artisan would have had reasonable expectation of success, as Smooker had taught that large libraries of particles could elicit immunity when administered as DNA vaccine.

Response to Argument – 103, Brunham/Johnston/Smooker

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Brunham/Johnston/Smooker does not Obviate the claims (pp. 35-36, paragraph bridging).

Such is not persuasive. Applicant is claiming a product by process, and not a method itself. There is nothing in the claims to distinguish the obtained composition from that of Johnston.

Applicant argues that the combination of Brunham/Johnston/Smooker offers a distinct approach for the library than presently taken than that cited by the Examiner (p. 35-36, paragraph bridging).

Such is not persuasive. The composition still reads on the claims and corresponds to a library. Moreover, whatever manner in which the Artisan recognizes will work is acceptable, just because something is more preferable to Applicant's eyes does not preclude the Artisan's ability to do other methods. Moreover a library of MOMP genes is a library of MOMP genes from these various viral strains.

Applicant argues that the combination of references is impermissible hindsight, because there is no specific motivation (p. 37, paragraph 1).

Such is not persuasive. KSR v. Teleflex precludes the argument of specific motivation.

Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,866,553 to Donnelly, et al., Patented 2/2/99, U.S. Patent No. 6,156,558 to Johnston, et al., Patented 12/5/00 and Smooker, et al. (2000) Vaccine, 18: 2533-40.

Donnelly teaches eliciting immune responses to papilloma virus via DNA constructs encoding papilloma virus gene products (e.g., ABSTRACT, TITLE). Further, several antigens are taught for such encoded genes, which may be used in combination (e.g. col. 5, paragraph 2). Still further, it is noted that papilloma virus is not only a virus, but a major cause of cancer in women (cervical cancer), and hence, such immunization is also against cancer.

Johnston teaches the use of the equivalent alpha-viral replicon particles, in vaccines. (E.g., ABSTRACT; col. 3, paragraph 4; col. 4, paragraph 2; cols. 7-8, paragraph bridging.) Moreover, Johnston demonstrates that the particles are sufficient to produce immune responses against foreign gene encoded proteins (e.g., FIGURE 3).

Smooker teaches a library of epitopes, expressed on separate plasmids (a library), for immunizing mice against Plasmodium chabaudi, a protozoan (ABSTRACT).

Hence, at the time of invention, it would have been obvious to modify the composition of Donnelly to contain different antigens of HPV in the alphaviruses of Johnston. The Artisan would have been motivated to do so to provide immunity against the virus HPV and cancer. Moreover, the Artisan would have had reasonable expectation of success, as Smooker had taught that large libraries of particles could elicit immunity.

Response to Argument – 103, Donnelly/Johnston/Smooker

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Donnelly/Johnston/Smooker does not obviate the claims (pp. 38, paragraph 2).

Such is not persuasive. Applicant is claiming a product by process, and not a method itself. There is nothing in the claims to distinguish the obtained composition from that of Johnston.

Applicant argues that the combination of references is impermissible hindsight, because there is no specific motivation (p. 39, paragraph 1).

Such is not persuasive. KSR v. Teleflex precludes the argument of specific motivation.

Claims 16 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,309,642 to Cutler, et al., Patented 10/30/01, U.S. Patent No. 6,156,558 to Johnston, et al., Patented 12/5/00 and Smooker, et al. (2000) Vaccine, 18: 2533-40.

Cutler teaches several antigens designed to elicit immunity to Candida (a yeast and fungus), which may be delivered a polynucleotides encoding the antigens (e.g., ABSTRACT, CLAIMS).

Johnston teaches the use of the equivalent alpha-viral replicon particles, in vaccines. (E.g., ABSTRACT; col. 3, paragraph 4; col. 4, paragraph 2; cols. 7-8, paragraph bridging.) Moreover, Johnston demonstrates that the particles are sufficient to produce immune responses against foreign gene encoded proteins (e.g., FIGURE 3).

Smooker teaches a library of epitopes, expressed on separate plasmids (a library), for eliciting immunity to organisms (ABSTRACT).

At the time of invention, it would have been obvious to modify the methods of Cutler, by making several alphaviral replicon particles as taught by Johnston to encode different antigens as taught by Cutler. The Artisan would have been motivated to do so to provide immunity to Candida, as Johnston taught that such DNA immunization would provide similar immunity. Moreover, the Artisan would have had a reasonable expectation of success, as Smooker taught that multiple antigens could be delivered to produce immune responses.

Response to Argument – 103, Cutler/Johnston/Smooker

Applicant's argument of 8/8/07 has been fully considered but is not found persuasive.

Applicant argues that the method produces a much better yield, allowing larger amounts of viral product to be produced, and as such Cutler/Johnston/Smooker does not obviate the claims (pp. 40, paragraph 2).

Such is not persuasive. Applicant is claiming a product by process, and not a method itself. There is nothing in the claims to distinguish the obtained composition from that of Johnston.

Applicant offers an alternative motivation to make a distinct composition, and therefore, argues that the Artisan would not make the present composition (p. 40, paragraph 3).

Such is not persuasive. KSR v Teleflex precludes arguments of specific motivation.

Conclusion

No Claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Kelly, Ph.D.
Examiner, USPTO, AU 1633
Patents Hoteling Program
Mailbox 2C70, Remsen Building
(571) 272-0729

Joel Wortman
AU1633